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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/887,505	07/02/1997	ROBERT L. KILKUSKIE	HYZ-040CIP	1117

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EXAMINER
TAYLOR, JANELL E

ART UNIT	PAPER NUMBER
1655	26

DATE MAILED: 01/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/887,505	Applicant(s) KILKUSKIE ET AL.	
	Examiner Janell Taylor Cleveland	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,42 and 43* is/are pending in the application.

4a) Of the above claim(s) *42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,25 and 27-31* is/are rejected.

7)☐ Claim(s) *22-24 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following Office Action is being made NON-FINAL. Although there is no new art being made of record, this is being done in order to clarify some of the rejections previously made, in particular that of claim 29. A Response to Arguments section follows. Please note that claims 32-41 were canceled in Paper #9 filed October 5, 1998. Although this cancellation was overlooked in the previous examination, the claims remain canceled and are not included in this Office Action.

Election/Restrictions

1. Newly submitted claims 42-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a pharmaceutical composition, which is considered a separate and distinct group which requires a separate search of the art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of

paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Cha et al.

Claim 1 is drawn to a synthetic oligonucleotide complementary to a portion of the 5' untranslated region of Hepatitis C virus and having a sequence selected from the group which consists of SEQ ID NOS: 5-8, 14-16, 23-24, 26-29, 31, 33, 36-37, 47, and 68-133.

Cha et al. disclose SEQ ID NO: 126 which is identical to SEQ ID NO: 117 of the instant application. In particular, bases 10-29 of Cha are identical to bases 1-20 of the instant application. Therefore, Claim 1 is fully anticipated by Cha et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2-6, 8-20, 25, 27, 28, and 30 are rejected under 35 U.S.C. 103(a) as being disclosed by Hogan, et al in US Patent 5,424,413 in view of Maertens et al. (US Patent 5,846,704).

These claims are drawn to an oligonucleotide comprising a sequence complementary to at least two non-contiguous regions of an HCV mRNA or genomic RNA.

Hogan discloses a nucleic acid hybridization probe having at least one nucleic acid strand which has at least two separate target specific regions that hybridize to a target nucleic acid sequence. (See Abstract, Drawing 4A). This patent also discloses the use of modified oligonucleotides, as well as therapeutic applications for oligonucleotides.

This patent does not disclose an HCV messenger or genomic RNA.

Maertens et al. disclose as their invention probes targeting sequences from the 5' untranslated region of HCV. (See Abstract).

One of ordinary skill in the art would have been motivated to target the probe of Hogan et al to an HCV messenger or genomic RNA because Maertens et al disclosed the importance of detecting HCV nucleic acids. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

5. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Seki et al (CA2104649).

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NO: 47 and 160.

The teachings of Hogan et al. and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Seki et al. disclose an oligonucleotide (SEQ ID NO: 6) identical to instant SEQ ID NO: 47. Seki et al also disclose an oligonucleotide (SEQ ID NO: 229) identical to instant SEQ ID NO: 160.

One of ordinary skill in the art would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the

oligonucleotides as discussed above because these would have clearly been useful in detecting HCV nucleic acids.

6. Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Cha et al (USPN 6,071,693).

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NOS: 122 and 117.

The teachings of Hogan and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Cha et al. disclose an oligonucleotide (SEQ ID NO: 126), identical to instant SEQ ID NO: 122.

One of ordinary skill in the art at the time of the invention would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the product as discussed above because these would have clearly been useful in detecting HCV nucleic acids.

Summary

Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Kamada et al. Claims 2-21, 25, 27-30 are rejected under 35 U.S.C. 103(a). Claims 22-24 and 26 are free of the prior art because they teach sequences which were not found in the prior art, but are objected to for depending from rejected claims.

Response to Arguments

7. Applicant's arguments filed November 24, 2001 have been fully considered but they are not persuasive. First, Examiner apologizes for the use of the word "method" to refer to product claims. This error has been clarified.

Applicant has also argued that the Hogan et al. reference teaches contiguous nucleic acids and therefore the rejection is inappropriate, as the claims read on noncontiguous nucleic acids. However, in column 3 of the Hogan et al. patent, it states that "The one or more nucleic acid molecules or the target nucleic acid may include nucleic acid adjacent the junction which does not form a duplex with the arm regions or the target regions or the target nucleic acid, and loops out from the junction. Alternatively, the target regions include along their length, or at the ends distant from the arm regions, nucleic acid which does not from a duplex with the target nucleic acid and therefore either loops from a duplex formed between the target nucleic acid and the target region, or extends as a single stranded region from the end of the target region." (lines 17-28). Therefore, Hogan et al. teaches that the nucleic acid need not be contiguous.

Applicant has also argued that the rejection of claim 21 is inappropriate because "Table 1A shows various non-obvious modifications to SEQ ID NO: 122, wherein modifications are made to the sequence. However, the Hogan reference was used to show that modifications were obvious, regardless of where in the nucleic acid they occur. (Col. 6, lines 36-62).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor whose telephone number is (703) 305-0273. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1655 via the PTO Fax Center using (703) 872-9306 (before final) or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland
Art Unit 1655
1/17/02

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600